

## TRANSMITTAL LETTER TO THE UNITED STATES

286166US0PCT

DESIGNATED/ELECTED OFFICE (DO/EO/US)

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)

CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

10/572963

INTERNATIONAL APPLICATION NO.

PCT/EP04/10297

INTERNATIONAL FILING DATE

September 15, 2004

PRIORITY DATE CLAIMED

November 13, 2003

TITLE OF INVENTION

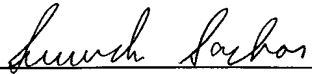
MULTILAYER PHARMACEUTICAL DOSAGE FORM CONTAINING A SUBSTANCE THAT ACTS IN A MODULATORY MANNER WITH REGARD TO THE RELEASE OF ACTIVE SUBSTANCES

APPLICANT(S) FOR DO/EO/US

Rosario LIZIO, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
  2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
  3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
  4. ☐ The US has been elected (Article 31).
  5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
    - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
    - b. ☒ has been communicated by the International Bureau.
    - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
  6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
    - a. ☒ is attached hereto.
    - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
  7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
    - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
    - b. ☐ have been communicated by the International Bureau.
    - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
    - d. ☒ have not been made and will not be made.
  8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
  9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
    - a. ☐ If the declaration is in a language other than the English language, it is accompanied by an English translation. The translation is accurate (37 CFR 1.69)
  10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).
  11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
  12. ☒ A copy of the International Search Report (PCT/ISA/210).
- Items 13 to 23 below concern document(s) or information included:**
13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
    - a. ☐ PTO-1449
    - b. ☐ Cited References
    - c. ☐ Statement of Relevancy
    - d. ☐ List of Related Cases.
  14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
  15. ☒ A **FIRST** preliminary amendment.
  16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
  17. ☒ An Application Data Sheet under 37 CFR 1.76.
  18. ☐ A substitute specification.
  19. ☒ A power of attorney and/or change of address letter.
  20. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
  21. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
  22. ☐ A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).
  23. ☒ Other items or information: Notice of Priority/PCT/IB/304/Request for Consideration

U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/572963</b>		INTERNATIONAL APPLICATION NO. PCT/EP04/10297		ATTORNEY'S DOCKET NUMBER 286166US0PCT	
The following fees are submitted:				<b>CALCULATIONS</b> <b>PTO USE ONLY</b>	
24. <input checked="" type="checkbox"/> Basic national fee..... \$300				\$300.00	
25. <input checked="" type="checkbox"/> Examination fee If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .... \$0 All other situations..... \$200				\$200.00	
26. <input checked="" type="checkbox"/> Search fee If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400 All other situations..... \$500				\$400.00	
<b>TOTAL OF 24, 25 AND 26 =</b>				<b>\$900.00</b>	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE		
- 100 =	/ 50 =		x \$250.00	\$	
<input type="checkbox"/> Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	15 - 20 =	0	x \$50.00	\$0.00	
Independent claims	1 - 3 =	0	x \$200.00	\$0.00	
MULTIPLE DEPENDENT CLAIMS (if applicable) <input type="checkbox"/> + \$360.00				\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$900.00</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
<b>SUBTOTAL =</b>				<b>\$900.00</b>	
<input type="checkbox"/> Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				+	\$
<b>TOTAL NATIONAL FEE =</b>				<b>\$900.00</b>	
<input type="checkbox"/> Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
<input type="checkbox"/> Petition fee of \$1,500.00 for Petition to Revive (37 CFR 1.137 (b)).				+	\$
<b>TOTAL FEES ENCLOSED =</b>				<b>\$900.00</b>	
				<b>Amount to be refunded:</b>	\$
				<b>Amount to be charged:</b>	\$
a. <input type="checkbox"/> A check in the amount of \$_____ to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. <u>15-0030</u> in the amount of \$_____ to cover the above fees.					
c. <input checked="" type="checkbox"/> The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>15-0030</u> . A duplicate copy of this sheet is enclosed.					
d. <input checked="" type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.					
<b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.					
SEND ALL CORRESPONDENCE TO:					
CUSTOMER NUMBER <b>22850</b>			SIGNATURE 		
Tel. (703) 413-3000 Fax. (703) 413-2220 (OSMMN 1/06)			NAME <b>Norman F. Oblon</b> <b>Surinder Sachar</b> <b>24,618</b> <b>Registration No. 34,423</b> REGISTRATION NUMBER		

MAR 21 2009

Docket No. 286166US0PCT

IN RE APPLICATION OF: Rosario LIZIO, et al.

SERIAL NO: New U.S. PCT Application Based on PCT/EP04/10297

FILED: Herewith

FOR: MULTILAYER PHARMACEUTICAL DOSAGE FORM CONTAINING A SUBSTANCE THAT ACTS IN A MODULATORY MANNER WITH REGARD TO THE RELEASE OF ACTIVE SUBSTANCES

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Transmitted herewith is an amendment in the above-identified application.

- ☒ No additional fee is required
- ☐ Small entity status of this application under 37 C.F.R. §1.9 and §1.27 is claimed.
- ☒ Additional documents filed herewith: Credit Card Payment Form for \$900.00/PCT Transmittal Letter/Application Data Sheet/Notice of Priority/Preliminary Amendment/English Translation of Specification/Declaration/PCT/IB/304/International Search Report/Request for Consideration

The Fee has been calculated as shown below:

CLAIMS	CLAIMS REMAINING		HIGHEST NUMBER PREVIOUSLY PAID	NO. EXTRA CLAIMS	RATE	CALCULATIONS
TOTAL	15	MINUS	20	0	x \$50 =	\$0.00
INDEPENDENT	1	MINUS	3	0	x \$200 =	\$0.00
		<input type="checkbox"/> MULTIPLE DEPENDENT CLAIMS			+ \$360 =	\$0.00
		TOTAL OF ABOVE CALCULATIONS				\$0.00
		<input type="checkbox"/> Reduction by 50% for filing by Small Entity				\$0.00
		TOTAL				\$0.00

- ☐ A check in the amount of \$0.00 is attached.
- ☐ Credit card payment form is attached to cover the fees in the amount of \$0.00
- ☒ Please charge any additional Fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.
- ☒ If these papers are not considered timely filed by the Patent and Trademark Office, then a petition is hereby made under 37 C.F.R. §1.136, and any additional fees required under 37 C.F.R. §1.136 for any necessary extension of time may be charged to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Norman F. Oblon

Registration No. 24,618

Customer Number

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Surinder Sachar

Registration No. 34,423

MTC Rec'd PCT/PTO 21 MAR 2003

DOCKET NO.: 286166US0PCT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Rosario LIZIO, et al.

SERIAL NO.: NEW U.S. PCT APPLICATION

FILED: HERewith

INTERNATIONAL APPLICATION NO.: PCT/EP04/10297

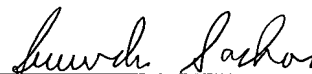
INTERNATIONAL FILING DATE: September 15, 2004

FOR: MULTILAYER PHARMACEUTICAL DOSAGE FORM CONTAINING A  
SUBSTANCE THAT ACTS IN A MODULATORY MANNER WITH REGARD TO THE  
RELEASE OF ACTIVE SUBSTANCES**REQUEST FOR CONSIDERATION OF DOCUMENTS  
CITED IN INTERNATIONAL SEARCH REPORT**Commissioner for Patents  
Alexandria, Virginia 22313

Sir:

In the matter of the above-identified application for patent, notice is hereby given that applicant(s) request that the Examiner consider the documents cited in the International Search Report according to MPEP §609 and so indicate by a statement in the first Office Action that the information has been considered. When the Form PCT/DO/EO/903 indicates both the search report and copies of the documents are present in the national stage file, there is no requirement for the applicant(s) to submit them (1156 O.G. 91 November 23, 1993).

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.Norman F. Oblon  
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